

Submitted Electronically

May 31, 2017

Document Processing Desk (DCI/PRD)
ATTN: Linsey Walsh
Registration Division
U.S. Environmental Protection Agency
Office of Pesticide Programs (7508P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

Dear Ms. Walsh,

**Subject: Fluometuron Technical, EPA Registration Number 82633-19
Generic Data Call-In Notice GDCI-035503-1628**

Wagner Regulatory Associates, Inc., as agent for Sharda Cropchem Ltd., is submitting the 90-day response to the generic DCI of the referenced product. In support of this request, the following documents are attached:

- Letter from Sharda Cropchem Ltd. appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Registration (8570-1)
- Registrant's Response Form
- Requirements Status and Registrant's Response Form

If you have any questions about this submission please contact the undersigned at 302-635-7289 or at email address cheryl@wagnerreg.com.

Respectfully submitted,



Cheryl Wagner
Agent for Sharda Cropchem Ltd.

Enclosures

Sharda Cropchem Limited

(Formerly known as Sharda Worldwide Exports Pvt. Ltd.)

Tel. : +91 22 66782800

Fax : +91 22 66782828 / 66782808

E-mail: shardain@vsnl.com

Regd. Office : Dornic Holm, 29th Road, Bandra (W), Mumbai - 400050. India.



ISO 9001: 2008 Reg. No: 690257



February 13, 2014

To: Whom it May Concern

Re: Sharda Cropchem Ltd

This letter serves as notification that Sharda Cropchem Ltd has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as the Agent on our company's behalf regarding state and/or federal regulatory matters as determined by Sharda Cropchem Ltd. The following employees of Wagner Regulatory Associates, Inc. are authorized to act on our behalf:

James Wagner
Email: james@wagnerreg.com
Phone: 302-635-7290

Cheryl Wagner
Email: cheryl@wagnerreg.com
Phone: 302-635-7289

Carrie Nolan
Email: carrie@wagnerreg.com
Phone: 302-635-7632

Barbarete Young-Henry
Email: barbarete@wagnerreg.com
Phone: 302-635-7279

Kt Woodall
Email: ktwoodall@wagnerreg.com
Phone: 302-635-7281


Correspondence can be addressed to any of the above employees at:

Wagner Regulatory Associates
P. O. Box 640
Hockessin, DE 19707-0640

Thank you for your time and assistance. Please feel free to contact Wagner Regulatory Associates should you have any questions.

Respectfully submitted,

For Sharda Cropchem Ltd


ASHISH R. BUBNA
(DIRECTOR)



cc: WRA, Inc.

SK
13/2/14

<p>United States Environmental Protection Agency Washington, DC 20460</p>	Registration	OPP Identifier Number
	Amendment	
	<input checked="" type="checkbox"/> Other	

Application for Pesticide - Section I

1. Company/Product Number 82633-19	2. EPA Product Manager Reuben Baris	3. Proposed Classification <input checked="" type="checkbox"/> None Restricted
4. Company/Product (Name) Sharda Cropchem Ltd./Fluometuron Technical	PM# 25	
5. Name and Address of Applicant (Include Zip Code) Sharda Cropchem Ltd. c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. 11603-31 Product Name: Cotoran Technical

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input checked="" type="checkbox"/> Other - Explain below.
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Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

90-Day Response to Data Call-In Notice GDCI-035503-1628

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Package wgt container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Bulk	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;"> <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled </div> <div style="text-align: center;"> <input type="checkbox"/> Other _____ </div> </div>			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Cheryl Wagner	Title Agent for Sharda Cropchem Ltd.	Telephone No. (Include Area Code) (302) 635-7289 (cheryl@wagnerreg.com)
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent for Sharda Cropchem Ltd.	
4. Typed Name Cheryl Wagner	5. Date 5/31/2017	

United States Environmental Protection Agency
Washington, D.C. 20460
DATA CALL-IN RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-4

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary.

1. Company Name and Address
SHARDA CROP CHEM LIMITED
P.O. Box 640
HOCKESSIN, DE 19707

2. Case # and Name
0049 - Fluometuron
Chemical # and Name: 035503
Fluometuron

3. Date and Type of DCI and Number
23-Mar-2017
GENERIC
ID # GDCL-035503-1628

4. EPA Product
Registration

5. I wish to cancel
this product
registration
voluntarily

6. Generic Data

6a. I am claiming a Generic Data
Exemption because I obtain the
active ingredient from the source
EPA registration number listed
below.

6b. I agree to satisfy Generic Data
Requirements as indicated on the
attached form entitled
"Requirements Status and
Registrant's Response."

7. Product Specific Data

7a. My product is an MUP and I
agree to satisfy the MUP
requirement on the attached form
entitled "Requirements Status and
Registrant's Response."

7b. My product is an EUP and I
agree to satisfy the EUP
requirement on the attached form
entitled "Requirements Status and
Registrant's Response."

82633-19

X

N/A

N/A

8. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative Cheryl R. Wagner Cheryl Wagner, Agent

9. Date

May 31, 2017

10. Name of Company

Sharda Cropchem Ltd.

11. Phone Number 302-635-7289

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SHARDA CROP CHEM LIMITED P.O. Box 640 HOCKESSIN, DE 19707		2. Case # and Name 0049 - Fluometuron Chemical # and Name: 035503 Fluometuron			3. Date and Type of DCI and Number 23-Mar-2017 GENERIC ID # GDCI-035503-1628				
4. Guideline Requirement Number	5. Study Title	P R O T O C O L	Progress Reports			6. Use Pattern	7. Test Substance	8. Time Frame (Months)	9. Registrant Response
			1	2	3				
850.4100	Nontarget Plant Protection Data Requirements (Conventional Chemical) Seedling Emergence and Seedling Growth	N				B,A	TEP	12	1
850.4150	Vegetative Vigor	N				B,A	TEP	12	1
	Residue Chemistry Data Requirements for Food Uses (Conventional Chemical)								
860.1650	Submittal of analytical reference standards (15)	N				B,A	TGAI, Degr	12	1
	Terrestrial and Aquatic Nontarget Organisms Data Requirements (Conventional Chemical)								
850.2100	Avian acute oral toxicity test (9, 10)	N				B,A	TGAI	12	1
850.3040	Field testing for pollinators (1, 2, 11, 17)	Y				B,A	TEP	24	1
835.4300	Aerobic aquatic metabolism	N				B,A	TGAI	24	1
10. Certification: I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law. Signature and Title of Company's Authorized Representative <u>Cheryl R Wagner</u> Cheryl Wagner Agent							11. Date May 31, 2017		
12. Name of Company Sharda Cropchem Ltd.							13. Phone Number 302-893-3847		

United States Environmental Protection Agency
Washington, D.C. 20460
REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

OMB Approval 2070-0174
EPA FORM 6300-3

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company Name and Address SHARDA CROPCHEM LIMITED P.O. Box 640 HOCKESSIN, DE 19707		2. Case # and Name 0049 - Fluometuron Chemical # and Name: 035503 Fluometuron				3. Date and Type of DCI and Number 23-Mar-2017 GENERIC ID # GDCI-035503-1628			
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			1	2	3				
850.6100	Environmental Chemistry Methods and Associated Independent Laboratory Validation (14)	N				B,A	TGAI	12	1
SS-1155	Residues in Pollen and Nectar/Field Residue Analysis (3, 16)	Y				B,A	TEP	24	1
SS-1311	Honey bee adult acute oral toxicity (5)	N				B,A	TGAI	12	1
SS-1312	Honey bee larvae acute oral toxicity (8)	N				B,A	TGAI	12	1
SS-1313	Honey bee adult chronic oral toxicity (6, 17)	Y				B,A	TGAI	12	1
SS-1314	Honey bee larvae chronic oral toxicity (7, 17)	Y				B,A	TGAI	12	1
SS-1319	Semi-field testing for pollinators (tunnel or colony feeding studies) (4, 12, 13, 17)	Y				B,A	TGAI or TEP	24	1

United States Environmental Protection Agency
Washington, D.C. 20460

FOOTNOTES AND KEY DEFINITIONS FOR GUIDELINE REQUIREMENTS

Case # and Name: 0049 - Fluometuron

DCI Number: GDCI-035503-1628

Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGA] = Technical grade of the active ingredient; [TW] = Treated wood

Use Categories Key:

A - Terrestrial food crop

B - Terrestrial feed crop

Footnotes: The following footnotes are referenced in column two (5. Study Title) of the Requirements Status and Registrant's Response form. These footnotes apply in addition to any test notes included in 40 CFR Part 158 with respect to the particular data requirement.

- 1 USEPA. 2012c. "Field Testing for Pollinators." Ecological Effects Test Guidelines OCSPP 850.3040. EPA 712-C-017.
- 2 Tier 3 study. The need for a field test for pollinators will be determined based on the results of lower-tiered tests and/or other lines of data and the need for a refined pollinator risk assessment.
- 3 Tier 2 study. The need for this study will be determined based on the results of lower-tiered studies and/or other lines of data and the need for a refined pollinator risk assessment.
- 4 Tier 2 study. The need for a semi-field test for pollinators (i.e., either a field-feeding test or a tunnel test) will be determined based on the results of lower-tiered tests and/or other lines of evidence, and the need for a refined pollinator risk assessment.
- 5 Tier 1 study. See the OECD 213: OECD Guidelines for the Testing of Chemicals. Honeybees, Acute Oral Toxicity Test. 213. http://www.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en
- 6 Tier 1 study. OECD has not yet finalized test guidelines for chronic studies, and efforts are underway to develop standardized guidelines for assessing the effects from chronic exposure to adult and larvae in the laboratory. Discussion of the study design elements for the 10-day adult toxicity test can be found in Appendix O of the European Food Safety Authority (EFSA) guidance document: EFSA. 2013. Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2013;11(7):3295, 266 pp. doi:10.2903/j.efsa.2013.3295. Available online at: <https://www.efsa.europa.eu/en/efsajournal/pub/3295>
- 7 Tier 1 study. OECD has not yet finalized test guidelines for chronic studies with honey bee larvae. OECD Draft Guidance Document Honey Bee (*Apis mellifera*) Larval Toxicity Test, Repeated Exposure. https://www.oecd.org/env/ehs/testing/Honeybee%20larval%20rep%20expo_REV%20following%20April%202015%20expert%20meeting_Draft%2020%20July%202015.pdf
- 8 Tier 1 study. OECD Test Guideline 237 may be used to develop a protocol for this study (OECD. 2013 Guidelines for Testing Chemicals. Honey bee (*Apis mellifera*) larval toxicity test, single exposure.) See: http://www.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en
- 9 The OCSPP 850.2100 guideline currently recommends the submission of a protocol for EPA review prior to initiation of tests conducted with passerine species. Data submitters are encouraged to consider the recommendations contained in relevant EPA reference documents (i.e., OCSPP 850.2100, EFED Guidance for Reviewing OCSPP 850.2100 Avian Oral Toxicity Studies Conducted with Passerine Birds, EFED Guidance for Use when Regurgitation is Observed in Avian Acute Toxicity Studies with Passerine Species) when preparing test protocols. A protocol does not need to be submitted to EPA for review prior to test initiation if it reflects these recommendations. If a data submitter elects to submit a protocol to EPA, in order to facilitate the review process, any aspects of a proposed study design that differ from this guidance should be noted and accompanied by a descriptive rationale which addresses why they are not expected to adversely impact the quality of the resulting study.
- 10 Testing is required with a passerine species.
- 11 See information and guidance identified in the EPA documents, (i) USEPA. 2012. White Paper in Support of the Proposed Risk Assessment Process for Bees. Submitted to the FIFRA Scientific Advisory Panel for Review and Comment September 11-14, 2012. Office of Chemical Safety and Pollution Prevention Office of Pesticide Programs Environmental Fate and Effects Division, Environmental Protection Agency, Washington DC; Environmental Assessment Directorate, Pest Management Regulatory Agency, Health Canada, Ottawa, CN; California Department of Pesticide Regulation; (ii) 2014 Guidance for Assessing Pesticide Risks to Bees. Office of Pesticide Programs United States Environmental Protection Agency, Health Canada Pest Management Regulatory Agency, California Department of Pesticide Regulation. June 19, 2014. https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf
- 12 Formal guidelines for semi-field tests do not yet exist; however, information that can help guide the development of a semi-field tunnel test protocol can be found at OECD 75, see: OECD. 2007. Series on Testing and Assessment Number 75. Guidance document on the honey bee (*Apis mellifera* L.) brood test under semi-field conditions. Environmental Directorate Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. ENV/JM/MONO(2007)22. 31-Aug-2007. [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2007\)22&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en)
- 13 For field-feeding studies see: Oomen et al. 1992: Oomen, P. A. A. DeRuijter and J. Van der Steen. 1992. Method for honey bee brood feeding tests with insect growth-regulating insecticides. Bul OEPP/EPPO Bulletin 22: 613-616.

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Case # and Name: 0049 - Fluometuron

DCI Number: GDCI-035503-1628

Key: [Degr] = Degradate; [d-EP] = diluted End-use product; [EP] = End-use product; [MET] = Plant metabolite; [MP] = Manufacturing-use product; [PAI] = Pure Active Ingredient; [PAIRA] = Pure active ingredient radio-labelled; [RAMET] = Radio-labeled plant metabolite; [ROC] = Residue of Concern; [TEP] = Typical end-use product; [TGAI] = Technical grade of the active ingredient; [TW] = Treated wood

- 14 Environmental Chemistry Methods and Independent Laboratory Validation are required for parent fluometuron in soil and water.
- 15 Analytical reference standards for parent fluometuron and the metabolites trifluoromethylaniline, CGA-236431, CGA-236432, and CGA-13211 must be submitted to EPA's National Pesticide Standards Repository as they have currently expired.
- 16 A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation. The following elements could be considered when developing study protocol(s) for the monitoring of residues in pollen/nectar.
Consideration of the range of application methods and environmental conditions (e.g., soil and hydric regimes) that the target crop(s) may be under.
Consideration of the attractiveness of the selected crop to pollinators.
Consideration of a collection schedule sufficient to allow for an understanding of the character of residues, in the pollen/nectar and/or plant tissues, over time.
Consideration of data sufficient to determine whether residues of the active ingredient and/or degradation product(s) accumulates in soil and is/are bioavailable for plant to uptake in a following planting, and therefore result in potential exposure to pollinators.
Consideration of the market proportion of the selected target crop(s).
- 17 A study protocol must be submitted to, and reviewed by the EPA, prior to study initiation.